K112624

510(k) Summary

OCT 10 2012

Comparison of Assays—Similarities and Differences

Immunoassay Comparison		
Feature	**Elecsys HE4 Assay**	**Predicate Device: Abbott Architect HE4 (K093957)**
General Assay Features		
Intended Use/ Indications for Use	The Elecsys HE4 assay is an immunoassay for the quantitative determination of HE4 in human serum and plasma. The assay is used as an aid in monitoring the recurrence or progressive disease in patients with epithelial ovarian cancer. Serial testing for patient HE4 assay values should be used in conjunction with other clinical findings used for monitoring ovarian cancer. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.	The ARCHITECT HE4 assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of the HE4 antigen in human serum. The assay is to be used as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer. Serial testing for patient HE4 assay values should be used in conjunction with other clinical methods used for monitoring epithelial ovarian cancer.
Assay Protocol	Quantitative sandwich immunoassay	Quantitative chemiluminsecent microparticle immunometric assay
Detection Protocol	Electrochemiluminescence	Chemiluminescence
Applications	18 minute application	Not reported

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510(k) Summary

Continued

Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HE4 Assay**	**Predicate Device: Abbott Architect HE4 (K093957)**
General Assay Features		
Instrument Platform	Elecsys 2010 and MODULAR ANALYTICS E170; Cobas e 411, cobas e 601 and cobas e 602	ARCHITECT *i* 2000, *i* 2000_{SR}, *i* 1000 and *i*1000_{SR}
Sample Volume	10 µL	75 µL for first test plus 25 µL for each additional test from the same sample cup. ≤ 3 hours on board: 150 µL for the first test plus 25 µL for each additional test from the same sample cup.
Sample Type	Human serum and plasma treated with K_2-EDTA, K_3-EDTA or lithium heparin.	Human serum
Reagents	The Elecsys HE4 assay is a sandwich immunoassay which includes a biotinylated monoclonal, murine HE4-specific IgG antibody as capture and a ruthenium labeled monoclonal, murine HE4-specific IgG antibody as signal.	The Abbott ARCHITECT HE4 is a two-step immunoassay for the quantitative determination of HE4 antigen in human serum using CMIA technology with flexible assay protocols, referred to as Chemiflex.
Calibrator	Elecsys HE4 CalSet, 2 levels	Abbott ARCHITECT HE4 Calibrators, 6 levels

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Continued

Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HE4 Assay**	**Predicate Devices: Abbott Architect HE4 (K093957)**
General Assay Features		
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: • After 28 days when using the same reagent lot. • After 7 days (when using the same reagent kit on the analyzer). • As required: e.g. quality control findings outside the specified limits	Once an ARCHITECT HE4 calibration is accepted and stored, all subsequent samples may be tested without further calibration unless onr or more of the following occur: • A reagent kit with a new lot number is used • Controls are out of range
Controls	Elecsys HE4 PreciControl	Abbott ARCHITECT HE4 Controls

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Continued

Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HE4 Assay**	**Predicate Device: Abbott Architect HE4 (K093957)**
General assay features		
Traceability / Standardization	The Elecsys HE4 Assay has been standardized against the HE4 EIA method from Fujirebio Diagnostics, Inc.	Not reported
Reagent Stability	Unopened at 2-8 °C—up to stated expiration date After opening at 2-8 °C—12 weeks On the analyzers—28 days	The ARCHITECT HE4 Reagent Kit must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C. When stored and handled as directed, the reagents are stable until the expiration date. The ARCHITECT HE4 Reagent Kit may be stored on board the ARCHITECT *i* System for a maximum of 30 days. Reagents may be stored on or off the ARCHITECT *i* system. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.

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510(k) Summary

Continued

Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HE4 Assay**	**Predicate Device: Abbott Architect HE4 (K093957)**
Labeled Performance Characteristics		
Measuring Range	15-1,5000 pmol/L	20-1,500 pmol/L
Precision	*Elecsys 2010/ cobas e 411:* Within-run (will be labeled Repeatability) n=84 1.8% CV @ 25.3 pmol/L 1.4% CV @ 45.7 pmol/L 1.8% CV @ 53.7 pmol/L 1.6% CV @ 142.0 pmol/L 1.6% CV @ 345.0 pmol/L 1.5% CV @ 779.0 pmol/L 1.3% CV @ 1437.0 pmol/L Total (will be labeled Intermediate) 3.7% CV @ 25.3 pmol/L 4.2% CV @ 45.7 pmol/L 4.2% CV @ 53.7 pmol/L 4.3% CV @ 142.0 pmol/L 3.4% CV @ 345.0 pmol/L 2.7% CV @ 779.0 pmol/L 4.2% CV @ 1437.0 pmol/L	*On the ARCHITECT i 2000$_{SR}$ System:* Within-run n=80 3.0% CV @ 49.0 pmol/L 2.2% CV @ 174.4 pmol/L 2.4% CV @ 687.3 pmol/L 3.1% CV @ 38.4 pmol/L 2.9% CV @ 189.7 pmol/L 2.9% CV @ 1114.7 pmol/L Total 3.3% CV @ 49.0 pmol/L 3.1% CV @ 174.4 pmol/L 3.3% CV @ 687.3 pmol/L 3.8% CV @ 38.4 pmol/L 3.1% CV @ 189.7 pmol/L 3.3% CV @ 1114.7 pmol/L

510(k) Summary

Continued

Comparison of Assays—Similarities and Differences, continued

<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Elecsys HE4 Assay</th><th>Predicate Device: Abbott Architect HE4 (K093957)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Analytical Sensitivity</td><td>On the e411:
Limit of Blank (LoB) 5.0 pmol/L
Limit of Detection (LoD) 15.0 pmol/L
Limit of Quantitation (LoQ) 20.0 pmol/L with a total allowable error of 30%</td><td>Limit of Blank: 0.1 pmol/L
Limit of Detection: ≤ 15 pmol/L
Functional Sensitivity: 20 pmol/L</td></tr>
<tr><td>Analytical Specificity</td><td><table><tr><th>Proteins (WFDC family)</th><th>Reactivity</th></tr><tr><td>Elafin/ SKALP at 54,500 pmol/L</td><td>0.025%</td></tr><tr><td>SLPI at 20,833 pmol/L</td><td>0.088</td></tr></table></td><td>No cross reactivity of above +/- LoD (<15 pmol/L) was seen with the following interferents tested:
CA 125
CA 15-3
CA 19-9
CEA
AFP</td></tr>
<tr><td>Hook Effect</td><td>There is no high-dose hook effect at HE4 concentrations up to 40,000 pmol/L.</td><td>There is no high-dose hook effect at HE4 concentrations up to 83,000 pmol/L.</td></tr>
</table>

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510(k) Summary

Continued

Comparison of Assays—Similarities and Differences, continued

<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Elecsys HE4 Assay</th><th>Predicate Device: Abbott Architect HE4 (K093957)</th></tr>
<tr><td colspan="3">Labeled Performance Characteristics</td></tr>
<tr><td>Limitations</td><td>The assay is unaffected by:

• Hemoglobin ≤ 1.0 g/dL
• Bilirubin up ≤ 66 mg/dL
• Triglycerides ≤ 2,000 mg/dL
• Biotin ≤ 50 ng/mL
• Rheumatoid Factor < 1,500 IU/mL
• HAMA < 805 ng/mL
• IgG ≤ 70 g/L
• In vitro tests were performed on 52 commonly used pharmaceuticals. No interference with the assay was found.
• In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies (such as HAMA), streptavidin or ruthenium can occur. These effects are minimized by suitable test design.</td><td>The assay is unaffected by:

• Hemoglobin 500 mg/dL
• Bilirubin up 20 mg/dL
• Triglycerides 3000 mg/dL
• Low protein 3 g/dL
• High protein 12 g/dL

Six specimens positive for HAMA and six specimens positive for Rheumatoid Factor (RF) were evaluated at the indicated interferent concentration ranges. The data are summarized in the following table.

<table><tr><th>Clinical Condition</th><th>Interferent Concentration Range</th><th>Mean % Recovery</th></tr><tr><td>HAMA</td><td>45-155 ng/mL</td><td>102</td></tr><tr><td>RF</td><td>21-445 IU/mL</td><td>103</td></tr></table></td></tr>
</table>

510(k) Summary

Continued

Comparison of Assays—Similarities and Differences, continued

<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Elecsys HE4 Assay</th><th>Predicate Device: Abbott Architect HE4 (K093957)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Clinical Sensitivity and Specificity</td><td>See below</td><td>See below</td></tr>
<tr><td>Internal Method Comparison (cobas e 601 vs. cobas e 411)</td><td colspan="2">
<table>
<tr><td>n = 131
Min = 17.0 pmol/L
Max = 1405.0 pmol/L</td><td>Passing/Bablok</td><td>Linear Regression</td></tr>
<tr><td>Slope</td><td>1.01
(1.00-1.02)</td><td>1.00
(0.994-1.01)</td></tr>
<tr><td>Intercept</td><td>-0.435
(-1.03-0.365)</td><td>2.29
(1.01-3.56)</td></tr>
<tr><td>Tau/r</td><td>0.979</td><td>0.999</td></tr>
</table>
</td></tr>
</table>

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510(k) Summary

Continued

Clinical Sensitivity and Specificity Elecsys HE4

Percent Change in HE4	Sensitivity (%) (n/N)	Lower CI (95%) for Sensitivity	Upper CI (95%) for Sensitivity	Specificity (%) (n/N)	Lower CI (95%) for Specificity	Upper CI (95%) for Specificity
0	69.14 (56/81)	57.61	80.88	57.83 (192/332)	52.35	63.44
5	62.96 (51/81)	50.63	75.61	68.07 (226/332)	62.71	73.08
10	54.32 (44/81)	42.13	66.67	74.70 (248/332)	69.47	79.32
14	50.62 (41/81)	39.34	62.09	77.41 (257/332)	72.52	81.76
15	49.38 (40/81)	38.28	60.48	78.31 (260/332)	73.68	82.51
20	46.91 (38/81)	35.44	58.44	84.04 (279/332)	80.12	87.76
25	39.51 (32/81)	28.84	51.23	87.05 (289/332)	83.56	90.34
50	24.69 (20/81)	16.00	34.52	95.78 (318/332)	93.65	97.64
75	17.28 (14/81)	9.20	26.75	97.59 (324/332)	95.92	99.02
100	14.81 (12/81)	7.50	23.94	97.89 (325/332)	96.29	99.19

510(k) Summary

Continued

Clinical Sensitivity and Specificity ARCHITECT HE4

Percent Change in HE4	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
10	57	75	40	85
14	54[a]	79[b]	43[c]	85[d]
20	48	84	48	85
25	41	87	49	83
50	31	94	60	82
75	21	97	66	80
100	18	98	69	80

a. Sensitivity is 100 X (number of sequential pairs with a ≥ 14% increase in HE4 concentration from patients with disease progression/total number of sequential pairs from patients with disease progression)

b. Specificity is 100 X (number of sequential pairs with < 14% increase in HE4 concentration from patients without disease progression/total number of sequential pairs from patients without disease progression)

c. PPV = 100 X(number of sequential pairs with ≥ 14% increase in HE4 concentration from patients with disease progression/total number of sequential pairs with a ≥ 14% increase in HE4 concentration)

d. NPV = 100 X (number of sequential pairs with < 14% increase in HE4 concentration from patients without disease progression/total number of sequential pairs with a < 14% increase in HE4 concentration)

510(k) Summary

Continued

Comparison of Calibrator Materials

Characteristic	CalSet for Elecsys HE4 Assay	Predicate Device: Elecsys hGH CalSet (K103221)
Intended Use	Elecsys HE4 CalSet is used for calibrating the quantitative Elecsys HE4 assay on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys hGH CalSet is used for calibrating the quantitative Elecsys hGH assay on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Same
Matrix	Equine serum	Human serum
Format	Lyophilized	Same
Stability	Unopened: • Store at 2 - 8°C up to the stated expiration date. After reconstitution: • At 2 - 8°C: 7 days. • At -20°C: 8 weeks (freeze only once). • On Elecsys 2010/**cobas** e 411 at 20 - 25°C: Up to 5 hours. • On MODULAR ANALYTICS E170/**cobas** e 601 and 602: Use only once.	Unopened: • Store at 2 - 8°C up to the stated expiration date. After reconstitution: • At 2 - 8°C: 7 days • At -20°C: 28 days (freeze only once). • On Elecsys 2010/**cobas** e 411 at 20 - 25°C: Up to 5 hours. On MODULAR ANALYTICS E170/**cobas** e 601: Use only once.
Handling	Dissolve the contents of one bottle carefully by adding exactly 1.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted calibrator into the empty labeled snap-cap bottles supplied.	Dissolve carefully the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted calibrator into the empty labeled snap-cap bottle supplied.

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510(k) Summary

Continued

Comparison of PreciControl Materials

Characteristic	Elecsys HE4 PreciControl	Predicate Device: Elecsys PreciControl Multimarker (K102157)
Intended Use	Elecsys PreciControl HE4 is used for quality control of Elecsys HE4 on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys PreciControl Multimarker is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Same
Format	Lyophilized	Same
Matrix	Human serum	Same
Analyte Concentration	Approximately 50 and 400 pmol/L	C-Peptide (synthetic): Approximately 2 and 10 ng/mL. Insulin (human recombinant from yeast): Approximately 25 and 80 µU/mL. ACTH (synthetic): Approximately 50 and 1,000 pg/mL. hGH (human recombinant from E. *coli*): Approximately 1 and 10 ng/mL.
Stability	Unopened: • Store at 2-8°C up to the stated expiration date. Reconstituted: • 2 - 8°C: 14 days • -20°C: 4 weeks (freeze only once) • On the analyzers at 20-25°C: up to 5 hours • At 20-25°C: 24 hours	Unopened: • Store at 2-8°C up to the stated expiration date. Reconstituted: • 2 - 8°C: 72 hours • -20°C: 31 days (freeze only once) • On the analyzers at 20-25°C: up to 5 hours
Handling	Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted control into the empty, labeled snap-cap bottles supplied or freeze aliquots in additional snap-cap bottles (ControlSet Vials). Attach the supplied labels to these bottles. Perform **only one** control procedure per aliquot.	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer the reconstituted control into empty, labeled snap-cap bottles supplied (ControlSet Vials) and freeze aliquots immediately in additional ControlSet Vials. Attach the supplied labels to these additional bottles. Perform **only one** control procedure per aliquot.

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510(k) Summary

Continued

Comparison of CalCheck 5 Materials

Characteristic	Elecsys HE4 CalCheck 5	Predicate Device: Elecsys DHEA-S CalCheck 5 (K103402)
Intended Use	The Elecsys HE4 CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HE4 reagent on the indicated Elecsys and cobas e immunoassay analyzers. For In Vitro Diagnostic Use Only.	The Elecsys DHEA-S CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys DHEA-S reagent on the indicated Elecsys and cobas e immunoassay analyzers.
Analyte	HE4	DHEA-S
Levels	Five	Same
Matrix	Equine serum	Human serum
Format	Lyophilized	Same
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4 and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.	Same
Stability	Unopened: • Store at 2-8 °C up to the stated expiration date. Reconstituted: • 20-25 °C: 5 hours	Unopened: • Store at 2-8 °C up to the stated expiration date. Reconstituted: 20-25 °C: 4 hours

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510(k) Summary

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Evaluations Summary

The Elecsys HE4 Immunoassay was evaluated for several characteristics, including precision, limit of quantitation, linearity, method comparison, interfering substances, and calibration stability.

The Elecsys HE4 CalSet, Elecsys PreciControl HE4 and HE4 CalCheck 5 were evaluated for value assignment and stability.

In addition, the Elecsys HE4 Immunoassays were evaluated in the clinical setting, completing a method comparison with clinically characterized samples, and measuring HE4 over time in subjects with ovarian cancer.

Confidentiality

Roche Diagnostics Corporation requests that the FDA not disclose the nature or existence of the premarket notification until the substantial equivalence decision has been reached.

Closing

We trust that the information provided in this Premarket Notification [510(k)] will support a determination of substantial equivalence for the Elecsys HE4 Test System.

If you should have questions or require further information, please do not hesitate to contact this office.

- Phone: (317) 521-3338
- FAX: (317) 521-2324

jane.phillips@roche.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 10 2012

Roche Diagnostics
c/o Dr. Jane Phillips
Regulatory Program Manager
9115 Hague Road
Indianapolis, IN 46250

Re: k112624
Trade/Device Name: Elecsys HE4 Assay
Elecsys HE4 CalSet
Elecsys PreciControl HE4
Elecsys HE4 CalCheck 5
Regulation Number: 21 CFR §866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: OIU, JIT, JJX
Dated: September 14, 2012
Received: September 17, 2012

Dear Dr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip

For Maria M. Chan, Ph. D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112624

Device Name: Elecsys HE4 Assay

Indications for Use:

The Elecsys HE4 assay is an immunoassay for the quantitative determination of HE4 in human serum and plasma. The assay is used as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer. Serial testing for patient HE4 assay values should be used in conjunction with other clinical findings used for monitoring ovarian cancer.

The electrochemiluminescence *i*mmunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112624

Indications for Use Form

510(k) Number (if known): K112624

Device Name: Elecsys HE4 CalSet

Indications for Use: Elecsys HE4 CalSet is used for calibrating the quantitative Elecsys HE4 assay on the Elecsys and **cobas e** immunoassay analyzers.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112624

Indications for Use Form

510(k) Number (if known): K112624

Device Name: Elecsys PreciControl HE4

Indications for Use: Elecsys PreciControl HE4 is used for quality control of the Elecsys HE4 immunoassay on Elecsys and **cobas e** immunoassay analyzers.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112624

Indications for Use Form

510(k) Number (if known): K112624

Device Name: Elecsys HE4 CalCheck 5

Indications for Use: The Elecsys HE4 CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HE4 reagent on the indicated Elecsys and cobas e immunoassay analyzers. For In Vitro Diagnostic Use Only.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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